Approved for use through 2/28/2010. OMB 0851:0021 U. S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number ATTORNEY'S DOCKET NUMBER TRANSMITTAL LETTER TO THE UNITED STATES 21059/0206916-US0 DESIGNATED/ELECTED OFFICE (DO/EO/US) U.S. APPLICATION NO. (if known, see 37 CFR 1.5) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 10/565,211 INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED PCT//B03/00860 11 March 2003 13 March 2002 TITLE OF INVENTION PROCESS FOR MANUFACTURING PHARMACEUTICAL COMPOSITION COMPRISES OF MYCOBACTERIUM W IN THE TREATMENT OF ASTHMA (OBSTRUCTIVE LUNG DISEASE) APPLICANT(S) FOR DO/FO/US Bakulesh Mafatlal Khamar et al Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. 2. X This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. X The US has been elected (Article 31). A copy of the International Application as filed (35 U.S.C. 371 (c)(2)) is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the international Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 9 X An English language translation of the annexes of the International Preliminary Examination Report under PCT 10. Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: An Information Disclosure Statement under 37 CFR 1.97 and 1.98. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. A preliminary amendment. An Application Data Sheet under 37 CFR 1.76. A substitute specification. A power of attorney and/or change of address letter. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825. A second copy of the published International Application under 35 U.S.C. 154(d)(4). A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

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U. S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number U.S. APPLICATION NO. (if known, see 37 CFR 1.5) INTERNATIONAL APPLICATION NO ATTORNEY'S DOCKET NUMBER 10/565 211 21059/0206916-US0 PCT/IB03/00860 20 Other items or information: The following fees have been submitted CALCULATIONS PTO USE ONLY 21. 22. Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$ All other situations 23. Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority \$100 \$ international Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB \$430 All other situations. \$540 TOTAL OF 21, 22 and 23 = 0.00 Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or in an electronic medium or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$270 for each additional 50 sheets of paper or fraction thereof. Total Sheets Extra Sheets Number of each additional 50 or fraction RATE thereof (round up to a whole number) - 100 = x \$270 Surcharge of \$130 for furnishing any of the search fee, examination fee, or the oath or declaration s 130.00 after the date of commencement of the national stage (37 CFR 1.492(h)). CLAIMS NUMBER FILED NUMBER EXTRA RATE Total claims 17 - 27 = x \$52 Independent claims 3.3= 0 x \$220 0.00 MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$390 TOTAL OF ABOVE CALCULATIONS = S 130.00 Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/4. SUBTOTAL = \$ 130.00 Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). TOTAL NATIONAL FEE = S 130.00 Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied 9 by an appropriate cover sheet (37 CFR 3.28, 3.31), \$40.00 per property \$ TOTAL FEES ENGLOSED = s 130.00 Amount to be \$ refunded: Amount to be \$ charged

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a. A check in the amount of \$ to cover the above fees is enclosed. b. X Please charge my Deposit Account No. 04-0100 in the amount of \$ 130.00 to cover the above fees. c. X The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit 04-0100 Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. The PTO-2038 should only be mailed or faxed to the USPTO. However, when paying the basic national fee, the PTO-2038 may NOT be faxed to the USPTO. ADVISORY: If filing by EFS-Web, do NOT attach the PTO-2038 form as a PDF along with your EFS-Web submission. Please be advised that this is not recommended and by doing so your credit card information may be displayed via PAIR. To protect your information, it is recommended paying fees online by using the electronic payment method. NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status. /Kenneth Ma 63,839/ for SIGNATURE SEND ALL CORRESPONDENCE TO: Jav P. Lessler NAME CUSTOMER NUMBER: 07278 41.151 REGISTRATION NUMBER